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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,066	12/15/2003	Eric Sommer	33304-pa	5244

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EXAMINER

HUYNH, KHOA D

ART UNIT PAPER NUMBER

3751

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/737,066	SOMMER ET AL.	
	Examiner	Art Unit	
	Khoa D. Huynh	3751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the spraying means as recited in claims 17, 18, 21 and 22.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 recites the method step of "manipulating said plurality of dispensing means to purge air in each of said dispensing lines". However, such claimed subject matter was not described in the instant specification. Applicant, in the instant specification, page 14, discloses "the assembly 20 located furthest from the end...is preferably returned to its original contracted position (Figure 7) after having expelled excess air". Applicant, however, does not disclose the detailed step of how the manipulation of the plurality of dispensing means to purge air in each of the dispensing lines was done. Therefore, it is reasonable for

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one skilled person to raise doubt that the inventor(s), at the time the application was filed, had possession of the invention as claimed.

4. Claims 16, 18, 20 and 22 are rejected under 35 U.S.C. 112, first paragraph; as failing to comply with the written description requirement. Each of the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of claims 16, 18, 20 and 22 recites the method step of "maintaining contents of said dispensing means at a desired temperature after filling". However, such claimed subject matter was not described in the instant specification. Applicant, in the instant specification, page 14, discloses the procedure for loading and removing the assembly 20. Applicant, however, does not disclose the detailed step of how the contents of the dispensing means are maintained at a desired temperature after filling. Therefore, it is reasonable for one skilled person to raise doubt that the inventor(s), at the time the application was filed, had possession of the invention as claimed.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites both the apparatus and the method of using the apparatus.

Such recitation renders the claims indefinite as they attempt to bridge two separate

statutory classes of invention. In other words, a manufacturer or seller of the claimed apparatus would not know from the claims whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus. Therefore, such claims are not sufficiently precise to provide competitors with an accurate determination of the mete and bounds of protection involved and are ambiguous. Claims 12-22 depend on claim 11 and are likewise indefinite.

Claim 11 also recites the method step of "manipulating said plurality of dispensing means to purge air in each of said dispensing lines". However, such claimed subject matter does not have any detailed support in the instant specification. Applicant, in the instant specification, page 14, discloses "the assembly 20 located furthest from the end...is preferably returned to its original contracted position (Figure 7) after having expelled excess air". Applicant, however, does not disclose the detailed step of how the manipulation of the plurality of dispensing means to purge air in each of the dispensing lines was done. Therefore, the reciting method step, "manipulating said plurality of dispensing means to purge air in each of said dispensing lines", renders the claims indefinite because the claimed subject matter was not actually disclosed, and thereby rendering the scope of claim 11 unascertainable. Claims 12-22 depend on claim 11 and are likewise indefinite.

Each of claims 16, 18, 20 and 22 recites the method step of "maintaining contents of said dispensing means at a desired temperature after filling". However, such claimed subject matter does not have any detailed support in the instant

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specification. Applicant, in the instant specification, page 14, discloses the procedure for loading and removing the assembly 20. Applicant, however, does not disclose the detailed step of how the contents of the dispensing means are maintained at a desired temperature after filling. Therefore, the reciting method step, "maintaining contents of said dispensing means at a desired temperature after filling", renders the claims indefinite because the claimed subject matter was not actually disclosed, and thereby rendering the scope of claim 11 unascertainable.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11-14, as presently and best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Raines et al. (5037390).

The Raines et al. reference discloses an apparatus (Fig. 2) for loading dispensing means such as syringes. The Raines et al. reference discloses a plurality of dispensing means (s1-s5) that are attached to separate dispensing lines (26, 27, etc., 30, 31, 32, etc.). The dispensing lines are flushed (col. 5, lines 63-68; col. 6, lines 1-4) to remove residues (inherently including bubbles of or excess air) in the dispensing lines. Each of the plurality of dispensing means is filled with a solution coming from each of the vial (at v1-v5).

The functional implications and statement of intended use have been fully considered. However, they appear not to impose any structural limitations patentably distinguishable over the Raines et al. apparatus which is capable of being used for loading dispensing means, i.e. syringes with thrombin and clotting proteins. Regarding claim 11, the method as claimed would be inherent during the normal used and operation of the Raines et al. apparatus.

The plurality of dispensing means is inherently capable of being clustered in pairs, i.e. s1 & s2, s3 & s4, and etc. with one of each pair receiving a solution, i.e. thrombin and the other receiving another solution, i.e. clotting proteins. Regarding claim 12, the method as claimed would be inherent during the normal used and operation of the Raines et al. apparatus.

Each of the dispensing means is equipped with a removable fitting (constitute by the tip portion of the syringe) for connecting each of the dispensing means to each of the dispensing lines. Regarding claim 13, the method as claimed would be inherent during the normal used and operation of the Raines et al. apparatus.

Each of the pair of dispensing means is securing in a frame (constitute by elements 12, 13, 14, 15, 16, 17). The frame includes a retaining member (constitute by elements 35). Regarding claim 14, the method as claimed would be inherent during the normal used and operation of the Raines et al. apparatus.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 11 and 12, as presently and best understood, are rejected under 35

U.S.C. 102(e) as being anticipated by Coelho et al. (6679300).

The Coelho et al. reference discloses an apparatus (Fig. 2) for loading dispensing means with thrombin and clotting protein. The Coelho et al. reference discloses a plurality of dispensing means (42, 76) that are attached to separate dispensing lines (constituted by the lines connecting to the thrombin unit 40 and clotting proteins unit 60). The dispensing lines are flushed (col. 10, lines 15-18) to remove excess air. Each of the plurality of dispensing means is filled with thrombin and clotting proteins. Regarding claim 11, the method as claimed would be inherent during the normal use and operation of the Coelho et al. apparatus.

The plurality of dispensing means is clustered in pairs (Fig. 1 shows a pair of dispensing means (42,76) with one of each pair receiving thrombin and the other receiving clotting proteins. Regarding claim 12, the method as claimed would be inherent during the normal use and operation of the Coelho et al. apparatus.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Coelho et al. (as discussed supra).

Regarding claim 13, even though the Coelho et al. reference does not specifically include a removable fitting as claimed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Coelho et al. dispensing means with a removable fitting. Such modification would be considered a mere choice of a preferred fitting connection on the basis of its suitability for the intended use especially since the Coelho et al. reference also discloses that the dispensing means will be decoupled from the sources once the dispensing means have been loaded with thrombin and clotting proteins (col. 10, lines 62-67). The method as claimed would be inherent during the normal use and operation of the modified Coelho et al. apparatus.

12. Claim 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Coelho et al. (as discussed supra) in view of Holm (5376079).

Regarding claims 14, 15 and 17, as schematically shown in Figure 1, the dispensing means are ensconced in a membrane. The Coelho et al. reference DIFFERS in that it does not specifically include a frame and a spraying means as claimed. Attention, however, is directed to the Holm reference which discloses a dispensing device (Fig. 1) for dispensing different substances from two syringes. The device includes a frame having retaining member (18,28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to have modified the modified Coelho et al. apparatus by employing a spraying device and a frame having a retaining member, in view of the teaching of Holm, in order to simultaneously dispense and mix thrombin and clotting proteins to generate an special mixed formula for treating a tissue related problem. The method as claimed would be inherent during the normal used and operation of the modified Coelho et al. apparatus.

Regarding claims 16 and 18, the modified Coelho et al. reference also discloses that the contents of the dispensing means are stored or maintained at room temperature after filling and prior to usage (Coelho et al., col. 11, lines 5-7). The method as claimed would be inherent during the normal used and operation of the modified Coelho et al. apparatus.

Allowable Subject Matter

13. Claims 19-22 are free of prior art and would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, and under 35 U.S.C. 112, 1st paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khoa D. Huynh whose telephone number is (571) 272-4888. The examiner can normally be reached on M-F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khoa D. Huynh
Primary Examiner
Art Unit 3751

HK
03/28/2006